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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 10/767,464   | 01/28/2004  | William T. Bodenhamer | 1965.025            | 3623             |
| 7590   | 12/13/2005  |                       | EXAMINER            |                  |
| Michael A. Slavin<br>McHale & Slavin, P.A.<br>2855 PGA Boulevard<br>Palm Beach Gardens, FL 33410 |             |                       | CHIN, CHRISTOPHER L |                  |
|  |             |                       | ART UNIT            | PAPER NUMBER     |
|  |             |                       | 1641                |                  |

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                        |  |
|------------------------------|------------------------|------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>    |  |
|                              | 10/767,464             | BODENHAMER, WILLIAM T. |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>        |  |
|                              | Christopher L. Chin    | 1641                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. ____ .   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____ .                                   |

**DETAILED ACTION**

***Specification***

1. The use of the trademark DARTEK and BYNEL (page 19) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. The disclosure is objected to because of the following informalities:
  - a.) At the top of page 15 of the specification, "tetramethy" should probably be changed to --tetramethyl-- to be correct.  
  
Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague. The preamble of the claim is not consistent with the body of the claim. The preamble recites "a process for producing a displacement assay" but the body of the claim appears to be claiming the steps for performing a displacement assay for the detection of antibodies. The last 2 lines of the claim appear to be detecting a

color and relating the presence of color to the presence of antibody. Perhaps the preamble of the claim should be amended to recite a process for performing a displacement assay? Step (c) of the claim is vague in reciting a "conjugated antibody" because it is not clear as to what the antibody is conjugated to. Step (f) is not clear as to what is reacting with the color producing agent to generate the color that is to be detected.

Claim 3 is vague. In line 2, "tetramethy" is misspelled. It should be --tetramethyl--.

Claim 4 is vague because it is not clear as to what the antibody is bound to via the soluble varnish.

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patents 4,434,236; 4,895,809; and 5,354,654 disclose displacement assays

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher L. Chin  
Primary Examiner  
Art Unit 1641

12/7/05